

AMENDMENTS TO THE CLAIMS

In the claims, please amend claims 1, 7-12, 15, 17 and 20-22 as indicated below.

Please cancel claims 2, 3, 18, 19 and 25-33.

1. (currently amended) A sustained release oral pharmaceutical dosage formulation comprising: (a) a core comprising: (i) ~~an opioid analgesic oxycodone or a pharmaceutically acceptable salt thereof~~; (ii) at least one pharmaceutical excipient; and (b) a delayed release coating surrounding the core consisting essentially of comprising: (i) about 30 to about 80 weight percent of the delayed release coating of a pH dependent material a first enteric coating agent; (ii) about 20 to about 70 weight percent of the delayed release coating of an inert processing aid and a second enteric coating agent; (iii) optionally a plasticizer; (iv) optionally an inert processing aid; and (c) an immediate release drug layer comprising: (i) oxycodone or a pharmaceutically acceptable salt thereof ~~an opioid analgesic~~; (ii) a binder; and (d) optionally a cosmetic coating wherein the pH dependent material consists of a first enteric coating that begins to dissolve or degrade at a pH of about 5 to about 7 and a second enteric agent that begins to dissolve or degrade at a pH of above 7.

2. (canceled).

3. (canceled).

4. (original) The sustained release dosage formulation as defined in claim 1 wherein the pharmaceutical excipient in the core is selected from the group consisting of binders, diluents, lubricants, emulsifiers, osmopolymers, osmotic agents, glidants, flavoring agents and combinations of the foregoing.

5. (original) The sustained release dosage formulation as defined in claim 1 wherein the pharmaceutical excipient in the core comprises a binder and a diluent.

6. (original) The sustained release dosage formulation as defined in claim 5 wherein the pharmaceutical excipient in the core further comprises a glidant and a lubricant.

7. (currently amended) The sustained release dosage formulation as defined in claim 5 wherein the binder is an osmopolymer ~~esopolymer~~.

8. (currently amended) The sustained release dosage formulation as defined in claim 5 wherein the binder is water soluble and has a viscosity of greater than 50,000 mPa when tested in a 2% aqueous solution at 20 $^{\circ}\text{C}$ ~~degree. C.~~

9. (currently amended) The sustained release dosage formulation as defined in claim 5 wherein the binder is water soluble and has a viscosity of greater than 75,000 mPa when tested in a 2% aqueous solution at 20 °C .degree. C.

10. (currently amended) The sustained release dosage formulation as defined in claim 1 wherein the first enteric coating agent begins to dissolve or degrade at a pH of about 5 to about 6 and the second enteric agent begins to dissolve or degrade at a pH of above 7 or is degraded in the gastrointestinal tract.

11. (currently amended) The sustained release dosage formulation as defined in claim 1 wherein the first enteric coating agent begins to dissolve or degrade at a pH of about 6 to about 7 and the second enteric agent begins to dissolve or degrade at a pH of above 8 or is degraded in the gastrointestinal tract.

12. (currently amended) The sustained release dosage formulation as defined in claim 10 wherein the second enteric agent begins to dissolve or degrade at a pH of about 11 to about a pH of 12.

13. (original) The sustained release dosage formulation as defined in claim 10 wherein the ratio of first enteric agent to the second enteric agent is about 1:5 to 5:1.

14. (original) The sustained release dosage formulation as defined in claim 13 wherein the ratio of first enteric agent to the second enteric agent is about 1:2 to about 1:4.

15. (currently amended) The sustained release dosage formulation as defined in claim 1 wherein the pH dependent material inert processing aid comprises about 35 20 to about 60 70 percent of the total weight of the delayed release coating.

16. (original) The sustained release dosage formulation as defined in claim 15 wherein the inert processing aid comprises about 30 to about 60 percent of the total weight of the delayed release coating.

17. (original) A sustained release oral pharmaceutical dosage formulation comprising: (a) a core comprising: (i) oxycodone or a pharmaceutically acceptable salt thereof an opioid analgesic; (ii) a diluent; (iii) a binder that is water soluble and has a viscosity of greater than 50,000 mPa when tested in a 2% aqueous solution at 20 °C degree C; and (b) a delayed release coating surrounding the core consisting essentially of comprising: (i) about 35 to about 60 weight percent based upon the total weight of the delayed release coating of a pH dependent material a first enteric coating agent that begins to dissolve at a pH of about 5 to about 6; (ii) about 30 to about 60 weight percent of an inert processing aid a second enteric coating agent that begins to dissolve at a pH of

above 8; (iii) an inert processing aid; (iv) optionally about 0.1 to about 15 weight percent based upon the total weight of the delayed release coating of a plasticizer; and (c) an immediate release drug layer comprising: (i) oxycodone or a pharmaceutically acceptable salt thereof an opioid analgesic; (ii) a binder; and (d) optionally a cosmetic coating wherein the pH dependent material consists of a first enteric coating that begins to dissolve or degrade at a pH of about 5 to about 7 and a second enteric agent begins to dissolve or degrade at a pH of above 8.

18. (canceled).

19. (canceled).

20. (currently amended) The sustained release dosage formulation as defined in claim 17 wherein the binder in the core has a viscosity of greater than 75,000 mPa when tested in a 2% aqueous solution at 20 $^{\circ}\text{C}$.

21. (currently amended) The sustained release dosage formulation as defined in claim 17 wherein the first enteric coating agent begins to dissolve or degrade at a pH of about 6 to about 7 and the second enteric agent begins to dissolve or degrade at a pH of above 9.

22. (currently amended) The sustained release dosage formulation as defined in claim 17 wherein the second enteric agent begins to dissolve or degrade at a pH of about 11 to about a pH of 12.

23. (original) The sustained release dosage formulation as defined in claim 17 wherein the ratio of first enteric agent to the second enteric agent is about 1:5 to 5:1.

24. (original) The sustained release dosage formulation as defined in claim 17 wherein the ratio of first enteric agent to the second enteric agent is about 1:2 to about 1:4.

25-33. (canceled).